

### **DETAILED ACTION**

The replacement drawings filed 9/15/2008 are acknowledged.

The Supplemental Amendments filed 12/2/2008 are acknowledged. Please note that the serial number listed on the top of the supplemental amendments and response filed 12/2/2008 incorrectly lists 10/696655 as the application serial number. The correct number is 10/697655.

### ***Information Disclosure Statement***

Acknowledgement is made of applicant's submitting information disclosure statements on 8/27/2008 and 9/15/2008. With the exception of those references which have been lined out, the submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Reference US 20060011443 on the IDS dated 8/27/2008 was lined out because the inventor name of the reference does not match that provided by Applicant on the IDS. US 20060011443 is drawn to a support housing for torque-transmitting mechanisms in a power transmission and is to Portell et al. Applicant lists the inventor as Fukushima.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ray Ackavan on December 3, 2008.

The application has been amended as follows:

**Claims:**

Claim 26 is to be replaced with the following:

Claim 26. A method for the treatment of a condition in a mammal, said method comprising administering to said mammal an effective amount of tranilast or a pharmaceutically acceptable salt thereof, wherein said condition is multiple sclerosis.

Claim 44 is to be amended as follows:

Claim 44. The method of claim 26, wherein said administering is selected from a group consisting of administering respiratorally, intratracheally, nasopharyngeally, intravenously, intraperitoneally, ~~nasopharyngeally, intravenously, intraperitoneally,~~ subcutaneously, intracranially, intradermally, intramuscularly, intraocularly, intrathecally, intracerebrally, intranasally, infusion, orally, rectally, via IV drip, patch and implant.

**REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The instant claimed method for the treatment of a condition in a mammal, said method comprising administering to said mammal an effective amount of tranilast or a pharmaceutically acceptable salt thereof, wherein said condition is multiple sclerosis (MS) is novel and non-obvious over the prior art. Tranilast is a known drug, however the method of treating MS with tranilast is novel. In terms of obviousness, there is a connection between iNOS inhibition and MS, however no prior art references teach or suggest a connection between tranilast and iNOS inhibition. Zappulla et al. ("Mast cells: new targets for multiple sclerosis therapy?" *Journal of Neuroimmunology*, **2002**, *131*, 5-20) teach that mast cell stabilizers, such as tranilast, *might* be effective and interfere with the central nervous system (CNS) inflammation process. Specifically the reference discloses that tranilast, amlexanox and sodium cromoglycate have the ability to effectively block IgE-mediated mast cell degranulation by binding to calcium-binding protein. The reference further states that sodium cromoglycate has been shown to prevent the increase of blood brain barrier permeability in rats following acute stress, but whether a similar effect might be seen in CNS inflammation has yet to be assessed (p.15, first full paragraph). Further, from the reference, it is unclear whether or not targeting mast cells will even be an effective means of treating multiple sclerosis. Therefore, due to the hypothetical nature of the reference, the reference does not render the instant invention obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Claims 26, 44-47, and 57-60 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney L. Klinkel whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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